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5.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	IsoTis OrthoBiologics, Inc.
TRADE NAME:	ACCELL TBM-R
COMMON NAME:	Bone Void Filler
CLASSIFICATION NAME:	Resorbable calcium salt bone void filler
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	MQV, MBP
PREDICATE DEVICES:	Accell Family of Products K061880 (Accell DBM100, Accell TBM, Accell A2i and Accell Connexus), and Grafton DBM-Flex K051195

5.1 Substantially Equivalence:

The Accell TBM-R is substantially equivalent in intended use, principal of operation and technological characteristics to the current Accell Family of Products (Accell DBM100, Accell TBM, Accell A2i and Accell Connexus); 510(K) - K061880.

5.2 Description of the Device Subject to Premarket Notification:

The Accell TBM-R is an extension to the Accell Family of Products 510(K) K061880. The Accell Family of Products, including Accell TBM-R, contain human demineralized bone matrix (ground, demineralized cortical bone). The Accell TBM-R is an addition to the Accell product family which has improved ease of use in handling characteristics and manual manipulation of the device.

5.3 Indication for Use:

The Accell TBM-R is intended for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The products are indicated for use as bone graft extenders, bone void fillers or bone graft substitutes in the extremities, pelvis and spine (i.e. posterolateral spine fusion). The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

5.4 Technical Characteristics:

The Accell TBM-R and Accell Family of Products (K061880) utilize ground and demineralized,

human cortical bone (DBM) in the formulation of the product. The DBM component exhibits osteoinductive potential in validated animal and/or *in vitro* models. It is unknown how the osteoinductive potential, measured in these validated models, will correlate with clinical performance in human subjects.

5.5 Performance Data:

All necessary verification testing has been performed for the Accell TBM-R product to assure substantial equivalence to the predicate device as well as safety and efficacy.

5.6 Osteoinductive Potential

Each lot of DBM used to manufacture the Accell TBM-R and the Accell Family of Products is tested for osteoinductive potential using an *in vitro* test. The *in vitro* assay has been validated to correlate to an athymic mouse osteoinductive potential assay. It is unknown how osteoinductive potential measured via the *in vitro* or athymic mouse assays will correlate with human clinical performance.

5.7 Viral Inactivation Validation

The methods for processing of the DBM contained in Accell TBM-R and the Accell Family of Products were evaluated for their viral inactivation potential. A selected panel of viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable inactivation potential of the processing methods for a wide range of potential viruses.

5.8 Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Accell TBM-R, has been determined by IsoTis OrthoBiologics to be substantially equivalent to an existing legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2008

Iso Tis Orthobiologics, Inc.
% Integra Lifesciences Corporation
Ms. Judith E. O'Grady
Senior VP, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K081817
Trade/Device Name: Accell TBM-
Regulation Number: 21 CFR 888.3045
Regulation Names: Resorbable calcium salt bone void filler device.
Regulatory Class: II
Product Code: MBP, MQV
Dated: June 25, 2008
Received: June 26, 2008

Dear Ms. O'Grady:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081817

Device Name: Accell TBM-R

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081817